NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NATALIE M. SANDERS, On Behalf of Herself and All Others Similarly Situated, and On Behalf of the General Public, Plaintiff, v. JOHNSON & JOHNSON, INC., a New Jersey Corporation, GYNECARE WORLDWIDE, ETHICON, INC., a division of JOHNSON & JOHNSON, and LIFECORE BIOMEDICAL, INC., Defendants.	Civ. No. 03-2663 (GEB) **OPINION**

BROWN, Chief Judge

This matter comes before the Court upon: (1) defendants Johnson & Johnson, Inc., Gynecare Worldwide, Ethicon, Inc. and Lifecore Biomedical, Inc.'s (collectively "Defendants") motion to strike the class action allegations set forth in plaintiff Natalie Sanders' ("Plaintiff") amended complaint ("Amended Complaint"); and (2) Plaintiff's cross-motion for partial class certification pursuant to Federal Rules of Civil Procedure Rule 23(b)(2) and (b)(3). The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332. The Court, having considered the parties' submissions, and for the reasons set forth below, will grant Defendants' motion to strike the class action allegations of the Amended Complaint and deny Plaintiff's cross-motion for partial class certification.

I. BACKGROUND

A. The Parties

Plaintiff is a resident and citizen of the State of Alabama. (Am. Compl. ¶16.) Defendant

Ethicon, Inc. is a company with its principal place of business located in New Jersey, and is in the business of designing, manufacturing and marketing medical devices and biological products for gynecological markets worldwide. (*Id.* ¶18; Defs.' Ans. to Am. Compl. (July 15, 2004) ¶7.) Defendant Gynecare Worldwide ("Gynecare") is a division of Ethicon, and has marketed, distributed and sold Gynecare Intergel Adhesion Prevention Solution ("Intergel"), the product at issue in this action. (Am. Compl. ¶¶13-14, 18-19; Defs.' Ans. to Am. Compl. (July 15, 2004) ¶¶4, 7-8.) Defendant Lifecore Biomedical, Inc. ("Lifecore") is a Minnesota corporation that has manufactured Intergel for distribution and sale, and has a business relationship with Defendant Johnson & Johnson, Inc. ("J&J"). (Am. Compl. ¶20-21; Def.'s Ans. to Am. Compl. (Aug. 3, 2004) ¶20-22.) Defendant J&J is a publicly traded corporation with its principal place of business located in New Jersey. (Am. Compl. ¶17; Defs.'Ans. to Am. Compl. (July 15, 2004) ¶6.)

B. Plaintiff's Claims

Intergel is a product that provides a "transient viscous, lubricous coating on the peritoneal surfaces following surgical procedures" and is used to reduce post-surgical adhesions. (*See* Webber Cert. Ex. 1.) Plaintiff alleges that on or about February 20, 2003, she underwent several gynecological procedures, and that Intergel was applied to her in the course of those procedures. (Am. Compl. ¶2.) After the procedures were completed, Plaintiff began suffering from extreme pain and other complications. (*Id.* ¶¶3-6, 10.) Plaintiff claims that the use of Intergel during her treatment caused the injuries that she allegedly suffered. (*Id.* ¶14.)

In March 2003, Gynecare issued a notice announcing the voluntary withdrawal of Intergel from the market. (*Id.* ¶¶32-33; Defs.' Ans. to Am. Compl. (July 15, 2004) ¶2.) Plaintiff brought this lawsuit on June 3, 2003. She claims that Defendants each participated in the design, manufacture, supply, distribution and/or sale of Intergel, and that the product caused the injuries that Plaintiff alleges. (Am. Compl. ¶22.) Plaintiff asserts claims of strict liability, negligence,

breach of express and implied warranty, fear of future product failure and misrepresentation. (*Id.* ¶¶36-71.) She seeks compensatory damages, punitive damages and equitable relief in the form of medical monitoring. (*Id.* ¶¶72-77.)

C. The Proposed Class

In addition to recovering for her own alleged injuries, Plaintiff also seeks to bring this action on behalf of a proposed class of individuals who have also used Intergel. That proposed class is defined as:

> All Affected Product Recipients who are citizens or residents of the United States, including their associated Derivative Claimants and Representative Claimants. The Class specifically includes persons who have or may have claims with respect to injuries not yet manifested. The Class shall expressly exclude any person or entity that entered into a settlement with Gynecare Worldwide and/or Ethicon, Inc. (which included a release) related to claims arising out of the implantation of an Affected Product.

("the Proposed Class") (Am. Compl. ¶25.) Plaintiff defines "Affected Product Recipients" as "persons in whose bodies one or more Affected Products have been or are now implanted in an operation or other surgical or gynecological procedure, whether or not such Affected Product has been or may in the future be removed." (*Id.*)

D. Procedural History

On or about September 15, 2004, Defendants J&J, Ethicon and Gynecare filed a motion to strike the class action allegations set forth in the Amended Complaint, which motion Defendant Lifecore also joined. On or about October 15, 2004, Plaintiff filed a brief in opposition to Defendants' motion, and filed a cross-motion seeking class certification pursuant to Federal Rules of Civil Procedure Rule 23(b)(2) and (b)(3). The parties have since completed briefing of both motions. This matter was reassigned to the undersigned on April 3, 2006. This Court has thoroughly reviewed all of the submissions from the parties and has decided the pending motions on the papers without oral argument pursuant to Federal Rules of Civil

Procedure Rule 78.

II. DISCUSSION

The parties' motions center on the question of whether Plaintiff may continue this lawsuit as a class action. The Court will therefore address Plaintiff's cross-motion to certify the Proposed Class before addressing Defendants' motion to strike Plaintiff's class action allegations from the Amended Complaint.

A. Plaintiff's Cross-Motion to Certify the Proposed Class

1. Standard of Review

In deciding whether to grant a motion to certify a class, a court must engage in "a thorough examination of the factual and legal allegations." *See Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 166 (3d Cir. 2001). "'[I]t may be necessary for the court to probe behind the pleadings before coming to rest on the certification question.'" *Id.* (quoting *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 160 (1982)). "'Before deciding whether to allow a case to proceed as a class action, . . . [the court] should make whatever factual and legal inquiries are necessary under Rule 23.'" *Id.* (quoting *Szabo v. Bridgeport Machs., Inc.*, 249 F.3d 672, 676 (7th Cir. 2001)).

2. General Requirements for Class Certification

"To be certified, a class must satisfy the prerequisites of Rule 23(a) and the 'parties seeking [class] certification must [also] show that the action is maintainable under Rule 23(b)(1), (2), or (3).'" *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 140 (3d Cir. 1998), *cert. denied*, 526 U.S. 1114 (1999) (quoting *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 614 (1997)). Plaintiff seeks certification pursuant to subdivisions (b)(2) and (b)(3).

For a class to be certified pursuant to Federal Rules of Civil Procedure Rule 23, the

plaintiff bears the burden of proving that the proposed class satisfies each of the four general requirements of Rule 23(a) and one of the prerequisites of Rule 23(b). *See Baby Neal v. Casey*, 43 F.3d 48, 55 (3d Cir. 1994). Rule 23(a) requires that:

> (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). Plaintiff seeks class certification pursuant to subdivisions (b)(2) and (b)(3) of Rule 23, and must therefore satisfy the requirements provided therein.

In their motion to strike Plaintiff's class action allegations, and in their opposition to Plaintiff's cross-motion to certify the Proposed Class, Defendants primarily argue that Plaintiff fails to satisfy the requirements of subdivisions (b)(2) and (b)(3). The Court will therefore begin by discussing the (b)(2) and (b)(3) requirements.

3. Requirements for (b)(3) Class Certification

For a proposed class to be certified pursuant to subdivision (b)(3), the plaintiff must show that:

> questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy.

Fed. R. Civ. P. 23(b)(3). The predominance requirement is not satisfied when there are a greater number of questions peculiar to the several categories of class members, and to individuals within each category, where such uncommon questions are significant. *Amchem Prods.*, 521 U.S. at 624. In considering whether the predominance requirement is satisfied, a court must consider whether there are significant common questions of law with respect to "each class member's cause of action or to the defense of such claims." *In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 174 F.R.D. 332, 340 (D.N.J. 1997).

Here, the Court has diversity jurisdiction over this case pursuant to 28 U.S.C. § 1332.

State substantive law therefore applies. *See Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938). A court exercising diversity jurisdiction must apply the choice of law rules of the forum state to determine which state's substantive laws to apply. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487 (1941). The Supreme Court has held that putative class members have a due process right to have their claims governed by the applicable state law. *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 821-23 (1985).

New Jersey choice-of-law principles require a government interest analysis, in which the forum court compares the interests of the states whose laws are potentially involved in the underlying action and determines which state has the greatest interest in having its laws applied. *In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 174 F.R.D. at 348 (citing *Gantes v. Kason Corp.*, 145 N.J. 478 (1996)). The home state of each of the Proposed Class's members has an interest in protecting its residents from in-state injuries and determining the scope of recovery available to them. *See id.* Plaintiff concedes as much – she does not claim that New Jersey law would apply to all members of the Proposed Class. Instead, she argues that the laws of the fifty states are sufficiently similar to satisfy the predominance requirement. (*See* Pl. Opp. Br. at 9-11.)

a. Plaintiff's Burden in Demonstrating Predominance Where the Laws of Different States Apply

Plaintiff seeks the certification of a nationwide class for which the laws of the fifty states could theoretically apply. In such a case, "[p]rior to certification, the district court must determine whether variations in state law defeat predominance." *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 750 (5th Cir. 1996). The plaintiff has the burden to "creditably demonstrate, through an 'extensive analysis' of state law variances, 'that class certification does not present insuperable obstacles.'" *Walsh v. Ford Motor Co.*, 807 F.2d 1000, 1017 (D.C. Cir. 1986), *cert. denied*, 482 U.S. 915 (1987) (quoting *In re School Asbestos Litig.*, 789 F.2d 996, 1010 (3d Cir.), *cert. denied*, 479 U.S. 915 (1986)).

An extensive analysis is required because "[i]f more than a few of the laws of the fifty states differ, the district judge would face an impossible task of instructing a jury on the relevant law . . . ." *In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1085 (6th Cir. 1996). "Differences in state law, no matter how slight, are important and must be determined prior to certification because such differences 'may swamp any common issues and defeat predominance.'" *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 208 (D. Minn. 2003) (quoting *Castano*, 84 F.3d at 741). *See also Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 618 (3d Cir. 1996), *aff'd*, *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591 (1997) (holding that the "radically different factual and legal issues" raised by each individual plaintiff's claim, "when exponentially magnified by choice of law considerations, eclipse any common issues in this case").

A plaintiff may satisfy his burden by identifying the relevant legal issues and categorizing the applicable law according to their differences, and convincing the court that those differences do not pose "insuperable obstacles" to managing the class. *See In re School Asbestos Litig.*, 789 F.2d at 1010. "Attempts at [the required] 'extensive analysis' often include model jury instructions and verdicts forms, as well as an attempt to group state laws by their relevant differences." *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 71 n.59 (S.D.N.Y. 2002). "Given the plaintiffs' burden, a court cannot rely on assurances of counsel that any problems with predominance or superiority can be overcome." *Castano*, 84 F.3d at 742.

b. Whether Plaintiff Has Satisfied Her Burden in Demonstrating Predominance of Common Issues

The Proposed Class encompasses anyone in the United States who has used Intergel, as well as those who may bring claims deriving from the users' actual or potential injuries resulting from such use. (*See* Am. Compl. ¶25.) The action is based on a number of legal claims, including strict liability, negligence, breach of express and implied warranty, fear of future product failure and misrepresentation. (*Id.* ¶¶36-71.) Plaintiff seeks compensatory damages,

punitive damages and equitable relief in the form of medical monitoring. (*Id.* ¶¶72-77.) In response to Plaintiff's claims, Defendants have asserted numerous defenses, including, among others, assumption of risk, comparative negligence, statute of limitations and the learned intermediary doctrine. (Defs.'Ans. to Am. Compl. (July 15, 2004) ¶¶35-54.) Plaintiff therefore has the burden of satisfying the predominance requirement through "extensive analysis" of the potentially applicable state laws with respect to each of these claims, defenses and forms of relief.

(1) Common Questions of Law and Fact Do Not Predominate Over Questions Affecting Individual Members of the Proposed Class

Plaintiff fails to satisfy the predominance requirement through "extensive analysis" of state laws governing the legal issues in this case. She argues that common factual and legal issues predominate over any variations in state laws. But rather than provide the Court with a summary of the potentially applicable state laws and describing the ways in which they differ, Plaintiff instead attempts a shortcut by relying on three district court cases of limited relevance, and offering a cursory comparison of state law with respect to only one of the legal issues raised in this case.

These efforts alone do not relieve the Court of its concerns that the individual legal and factual issues in this case predominate over the common ones. Considering the breadth of the Proposed Class, the numerous legal claims and defenses raised by the parties and the factual inquiry required for deciding those legal questions, the Court believes that common legal and factual questions would not predominate over individual ones. A cursory consideration of some of the relevant legal issues suggests that there are significant variations in at least some of the potentially applicable state laws.

States, for example, provide different formulations concerning negligence and its related concepts, and at least in some circumstances, those differences "can be important[.]" *See In re*

Rhone-Poulenc Rorer Inc., 51 F.3d 1293, 1300-01 (7th Cir. 1995) (citing representative cases from various states). Plaintiff asserts a claim of strict products liability, but not all states recognize such a claim. *See e.g. Cline v. Prowler Indus. of Md., Inc.*, 418 A.2d 968, 980 (Del. 1980). Similarly, not all states recognize a claim for mental distress resulting from fear of future product failure. *See e.g. Contreras v. Thor Norfolk Hotel, LLC*, 292 F. Supp. 2d 798, 801-02 (E.D. Va. 2003) (applying Virginia law); *Brewton v. Reichhold Chems., Inc.*, 707 So.2d 618, 620 (Miss. 1998); *Villari v. Terminix Int'l, Inc.*, 663 F. Supp. 727, 734 (E.D. Pa. 1987) (applying Pennsylvania law). With respect to Plaintiff's breach of warranty claims, states differ as to the requirements for establishing such claims. *Compare e.g. Energy Investors Fund, L.P. v. Metric Constructors, Inc.*, 525 S.E.2d 441, 446 (N.C. 2000) (holding that privity is required in a claim for breach of implied warranty) *with Taylor v. Ford Motor Corp.*, 408 S.E.2d 270, 272 (W. Va. 1991) (noting that the requirement of privity of contract has been abolished in West Virginia). *See also Walsh*, 807 F.2d at 1016 (rejecting appellees' claim that there are no variations in state warranty laws by noting the "general, unstartling statement made in a leading treatise: 'The Uniform Commercial Code is not uniform'") (citations omitted).

There are also differences in state laws concerning the defenses raised by Defendants. For example, not all jurisdictions recognize the learned intermediary doctrine. *See Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 767 n.3 (Ky. 2004) (identifying thirty-four states that have specifically adopted the learned intermediary rule by common law decision); *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 852 (10th Cir. 2003) (observing that, including decisions by federal courts exercising diversity jurisdiction, the learned intermediary doctrine has been adopted in prescription medicine cases in forty-five states) (citing *Vitanza v. Upjohn Co.*, 778 A.2d 829, 838 n.11 (Conn. 2001)).

State laws also vary with respect to the relief that Plaintiff seeks, including medical monitoring and punitive damages. *See e.g. Lewallen v. Medtronic USA, Inc.*, 2002 WL 31300899, at *5 (N.D. Cal. Aug. 28, 2002) ("[p]articularly where plaintiffs are asserting a

relatively novel claim for relief [–] such as medical monitoring – the differences in state law are likely to be substantial"); *Dhamer v. Bistol-Meyers Squibb Co.*, 183 F.R.D. 520, 533 (N.D. Ill. 1998) (stating that "the elements a plaintiff must prove to establish a right to medical monitoring differ among the states" and outlining a number of those differences). *See also In re Stucco Litig.*, 175 F.R.D. 210, 216 (E.D.N.C. 1997) ("[s]tate punitive damages law varies not only in terms of the conduct required to obtain punitives, but also in terms of the burden of proof required") (comparing statutory requirements for punitive damages in several states) (internal citations omitted); *Mack v. Gen. Motors Acceptance Corp.*, 169 F.R.D. 671, 678 (M.D. Ala. 1996) ("the resolution of the damages issues on the state law claims would also be difficult because the plaintiff seeks punitive damages on behalf of the class [and] [a]s the decision of the United States Supreme Court . . . makes clear, the treatment of punitive damages varies from state to state") (citing *BMW of North America v. Gore*, 517 U.S. 559 (1996)).

Individual fact questions pose a further obstacle to certifying the Proposed Class, even though Plaintiff alleges a number of facts that members of the Proposed Class would share in common. Those common facts concern Defendants' conduct in developing, manufacturing and testing Intergel, the alleged dangers of the product and Defendants' disclosures or lack of disclosures of those potential dangers. (Am. Compl. ¶26.) But although there would be some common factual issues between members of the Proposed Class, they would not predominate over the individualized ones. In proving their claims, class members would have to provide facts showing the circumstances of how they were injured. Those facts include their reasons for using Intergel, whether prior medical conditions caused their alleged injuries, what they understood about the risks of using Intergel when they used the product and the adequacy with which their physicians performed the surgery resulting in the use of the product. *See e.g. In re Am. Med. Sys.*, 75 F.3d at 1081 ("[p]roofs as to strict liability, negligence, failure to warn, [and] breach of express and implied warranties will also vary from plaintiff to plaintiff because complications with an AMS device may be due to a variety of factors, including surgical error, improper use of

the device, anatomical incompatibility, infection, device malfunction, or psychological problems"). *See also Georgine*, 83 F.3d at 627 ("[factual] [d]ifferences in amount of exposure and nexus between exposure and injury lead to disparate applications of legal rules, including matters of causation, comparative fault, and the types of damages available to each plaintiff"); *Castano*, 84 F.3d at 743 n.15 (holding that differences in nicotine exposure, class members' knowledge about the effects of smoking and their reasons for smoking "impact[] the application of legal rules such as causation, reliance, comparative fault, and other affirmative defenses"); *Gunnells v. Healthplan Servs., Inc.*, 348 F.3d 417, 438 (4th Cir. 2003) ("the affirmative defenses of comparative negligence [and] assumption of risk . . . pose significant obstacles to class certification"); *Lewallen*, 2002 WL 31300899, at *4 (holding that common issues did not predominate in a medical product liability case because of individualized fact issues concerning each claimant's medical history, what each claimant knew about the product's risks, the course of treatment taken and issues relating to causation). These individualized factual issues, coupled with the individual application of different state laws for members of the Proposed Class, would swamp any common issues of fact between the class members.

(2) The Cases on Which Plaintiff Relies Do Not Support Her Argument That the Predominance Requirement Is Satisfied in This Case

Plaintiff relies on three district court decisions in arguing that the predominance requirement is satisfied. Those decisions, however, have little persuasive value in this case. Plaintiff first cites *In re Copley Pharm., Inc.*, 158 F.R.D. 485 (D. Wyo. 1994), for the proposition that "the standards for ordinary negligence do not 'significantly differ throughout the country, and the differences that do exist can be remedied through careful instructions to the jury.'" (Pl.'s Opp. Br. at 3-4 (quoting *Copley*, 158 F.R.D. at 141).) According to Plaintiff, "the *Copley* court explicitly held that 'common issues predominate the [p]laintiffs' claims for strict liability, negligence, negligence per se, breach of warranties, and the request for declaratory relief.'" (*Id.*

at 4 (quoting *Coplely*, 158 F.R.D. at 142).)

The *Copley* decision, however, relied heavily on *Wadleigh v. Rhone-Poulenc Rorer, Inc.*, 157 F.R.D. 410 (N.D. Ill. 1994), which was subsequently reversed on appeal. The district court in *Wadleigh* granted class certification with respect to the plaintiffs' negligence claim in a products liability case. *Wadleigh*, 157 F.R.D. at 419-20. The court found that "the definition of ordinary negligence is substantially identical in all jurisdictions." *Id.* at 419. The Seventh Circuit Court of Appeals reversed that decision, and in doing so, addressed – and rejected – the district court's characterization of the differences in state law on negligence.

According to the Court of Appeals, the *Wadleigh* decision was based on "[t]he assumption . . . that the common law of the 50 states and the District of Columbia, at least so far as bears on a claim of negligence against drug companies, is basically uniform and can be abstracted in a single instruction." *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1300 (7th Cir. 1995) (Posner, C.J.). The Court of Appeals rejected that finding, instead making the following observation:

> The law of negligence, including subsidiary concepts such as duty of care, foreseeability, and proximate cause, may as the plaintiffs have argued forcefully to us differ among the states only in nuance, though we think not . . . . But nuance can be important, and its significance is suggested by a comparison of differing state pattern instructions on negligence and differing judicial formulations of the meaning of negligence and the subordinate concepts.

Id. (citations omitted). The Court agrees with the Seventh Circuit Court of Appeals' assessment, and therefore finds the decision in *Copley*, based as it is on *Wadleigh*, to be of little persuasive value.

Plaintiff also cites *In re Telectronics Pacing Systems, Inc.*, 172 F.R.D. 271 (S.D. Ohio 1997), for the proposition that "courts have held [that] if the elements of the cause of action are the same and the legal standards on 'important/meaningful/significant/pivotal' issues are substantially similar, the state laws can be grouped for purposes of class certification." (Pl.'s Opp. Br. at 10 (citing *In re Telectronics*, 172 F.R.D. at 292).) But Plaintiff has not grouped the relevant state laws – she only assures the Court that it can be done. In contrast, the plaintiffs in

Telectronics provided the district court with a comparison of the relevant state laws, as well as model jury instructions, and sought certification of subclasses based on the differences between them. *See Telectronics*, 172 F.R.D. at 291 ("Plaintiffs have divided the subclasses to reflect the forty-six jurisdictions that permit the introduction of state-of-the-art evidence and two jurisdictions which do not") ("Plaintiffs state that forty-seven jurisdictions permit plaintiffs in product liability actions to bring negligence claims"), 292 ("Upon review of the case law and pattern jury instructions from the various states, we find this [issue of proximate causation to be] a distinction without a difference"). Plaintiff has not prepared a comparable summary of the applicable state laws (except with respect to medical monitoring), nor provided the Court with model jury instructions and verdict forms, and it is not the Court's job to extensively analyze state law to determine whether Plaintiff's assurances are warranted.

Plaintiff also relies on *In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.*, 2003 WL 1589527 (D. Minn. March 27, 2003). There, in a nationwide products liability action involving numerous common law claims, the court conditionally certified a class for those who allegedly suffered personal injury and another for purposes of medical monitoring. *St. Jude*, 2003 WL 1589527, at *4-8. Plaintiff argues that, similar to *St. Jude*, the present action concerns only one product, and as a result "[t]he causation question here is far simpler and unitary than in any of the cases that [the defendant] cites, and . . . is not an overarching issue requiring individual proof." (Pl. Opp. Br. at 9 (quoting *St. Jude*, 2003 WL 1589527, at *7).)

The *St. Jude* court, however, later decertified the personal injury class because it found that the variations in state law would make the class action unmanageable. *St. Jude*, 2004 WL 45504, at *3 (D. Minn. Jan. 5, 2004), *rev'd on other grounds*, 425 F.3d 1116 (8th Cir. 2005) ("[g]iven the significant differences in state law and the number of plaintiffs' claims, combined with potential individual differences among the plaintiffs, the Court can no longer find that a class action would be the superior method of adjudication of these disputes"). As for the medical monitoring class, the Eighth Circuit Court of Appeals reversed the district court's certification of

that class. *St. Jude*, 425 F.3d at 1122 ("[s]imply put, the medical monitoring class presents a myriad of individual issues making class certification improper").

(3) Plaintiff's Analysis of State Laws Concerning Medical Monitoring Fails to Show That Common Issues Predominate Over Individualized Ones

Despite the number of legal issues that this case presents, Plaintiff has attempted to analyze variations in state laws with respect to only one of them, namely, whether a plaintiff is required to prove personal injury in a claim for medical monitoring. Plaintiff provides a chart dividing the states into three categories: (1) states that recognize claims for medical monitoring in the absence of physical injury; (2) states that recognize such claims with proof of physical injury; and (3) states that have rejected or not yet recognized such claims. (Pl. Opp. Br. at 12.) Plaintiff borrows this summary from the *St. Jude* district court. She does so, it appears, without having performed her own research on the subject. (*See id.* (classifying in the third category eighteen states not mentioned by the *St. Jude* court, but with no explanation of the law in those states).)

Assuming for the moment that Plaintiff's survey is accurate, it is not enough to satisfy her burden in showing a predominance of common issues. First, Plaintiff fails to address whether important variations in state law remain even within the classifications that she provides. For example, a number of states that require a showing of injury require proof of an underlying tort. *See e.g. Hinton ex. rel. Hinton v. Monsanto Co.*, 813 So.2d 827, 828 (Ala. 2001) (holding that medical monitoring is not available without proof of an underlying tort); *Badillo v. Am. Brands, Inc.*, 16 P.3d 435, 440 (Nev. 2001) (same). For those states, the Court would have to determine whether the laws governing the claimants' asserted tort claims vary and, if so, separately apply the laws of the respective states.

Second, states that permit medical monitoring in the absence of physical injury may differ in the required elements of proof. *Compare Bourgeois v. A.P. Green Indus., Inc.*, 716 So.2d 355,

360 (La. 1998) (requiring proof of "[*s*]*ignificant* exposure to a *proven* hazardous substance" resulting in "a *significantly* increased risk of contracting a serious latent disease") (emphasis added) *with Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979 (Utah 1993) (requiring "exposure [] to a toxic substance, . . . resulting in an increased risk [] of a serious disease, illness or injury").

In addition to these legal issues, there would also be individualized fact issues that the parties would have to address. Regardless of whether physical injury is required for a medical monitoring claim, and whether the claim is considered a cause of action or a remedy, each claimant would have to show that Intergel caused the alleged injury or risk of injury. The fact that Intergel is used in surgical procedures, however, raises a number of related factual issues, including whether the alleged injury was caused by the medical condition that necessitated the claimant's surgery, and whether the surgery itself caused the alleged injury.

Plaintiff seeks certification of a nationwide class involving numerous claims, defenses and forms of relief. She has failed, however, to provide the requisite analysis of the applicable state laws to show that variations in those laws would not "swamp any common issues and defeat predominance." *Castano*, 84 F.3d at 741. She has also failed to explain how the Court could manage the individualized factual issues in this products liability action without defeating the efficiency goals of class actions. *See id.* at 744 (requiring the district court "to consider how the plaintiffs' [] claims would be tried, individually or on a class basis"). Plaintiff fails to show that common issues predominate over individualized ones, and certification of the Proposed Class pursuant to Rule 23(b)(3) is therefore inappropriate.

4. Requirements for (b)(2) Class Certification

Plaintiff also seeks certification of the Proposed Class pursuant to Rule 23(b)(2) for purposes of medical monitoring. A class action is maintainable under Rule 23(b)(2) when "the party opposing the class has acted or refused to act on grounds generally applicable to the class,

thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole . . . ." Fed. R. Civ. P. 23(b)(2). "Subsection (b)(2) class actions are 'limited to those class actions seeking primarily injunctive or corresponding declaratory relief.'" *Barnes*, 161 F.3d at 142 (citations omitted).

Class certification under (b)(2) requires that the proposed class be cohesive. *Id.* at 143. In *Barnes*, the Third Circuit Court of Appeals explained that the cohesiveness requirement for (b)(3) classes, as articulated by the Supreme Court in *Amchem Prods.*, applies to (b)(2) classes as well. *Id.* at 142-43. According to the Court of Appeals, "[w]hile 23(b)(2) class actions have no predominance or superiority requirements, it is well established that the class claims must be cohesive." *Id.* at 143.

The *Barnes* court noted two reasons why courts must determine whether a proposed (b)(2) class is cohesive before certifying the class. "First, unnamed members with valid individual claims are bound by the action without the opportunity to withdraw and may be prejudiced by a negative judgment in the class action." *Id.* "[T]he court must ensure that significant individual issues do not pervade the entire action because it would be unjust to bind absent class members to a negative decision where the class representatives's claims present different individual issues than the claims of the absent members present." *Id.* (citations omitted). "Indeed, a (b)(2) class may require more cohesiveness than a (b)(3) class . . . because in a (b)(2) action, unnamed members are bound by the action without the opportunity to opt out." *Id.* at 142-43.

Second, "'the suit could become unmanageable and little value would be gained in proceeding as a class action . . . if significant individual issues were to arise consistently.'" *Id.* at 143 (quoting *Santiago v. City of Phila.*, 72 F.R.D. 619, 628 (E.D. Pa. 1976)). To avoid these problems, the Third Circuit has "committed to the district court the discretion to deny certification in Rule 23(b)(2) cases in the presence of 'disparate factual circumstances.'" *Geraghty v. U.S. Parole Comm'n*, 719 F.2d 1199, 1205-06 (3d Cir. 1983).

a. Plaintiff Fails to Demonstrate That the Proposed Class Is Cohesive

For reasons already explained, there are too many individualized issues of law and of fact for the Proposed Class to be considered cohesive. Class members would be subject to different state laws governing the numerous claims, defenses and forms of relief in this case, and Plaintiff has failed to demonstrate that those difference can be managed in a practical and efficient manner. *See In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 147 (E.D. La. 2002) (denying class certification of a medical monitoring class because "the record in this case does not presently contain any review or summary of the various applicable or relevant state laws" and "variations involving proof of causation, the effect of warnings, the significance of the defendants' direct marketing to consumers, and other similar issues may swamp any common issues and defeat cohesiveness").

Moreover, there are numerous individualized questions of fact that undercut Plaintiff's claim of cohesiveness. Those questions include, at the very least, how individual class members were injured, what alternative causes may have led to their alleged injuries and the extent of those injuries. *See Barnes*, 161 F.3d at 144-49 (affirming decertification of a medical monitoring class because there were numerous individualized fact questions concerning causation, comparative negligence, plaintiffs' knowledge of the alleged dangers of smoking and whether claimants required medical monitoring).

Finally, Plaintiff has offered no basis for the Court to find that medical monitoring would be appropriate in this case. She seeks medical monitoring in order to "watch for side effects and future injuries as a result of the implantation of Intergel" and "collect data" concerning those possible effects. (Pl. Opp. Br. at 2.) There is no evidence, however, of any recommendations from the medical community for a medical monitoring program or clinical study of the effects of Intergel on its users. In such a case, "the courts should not attempt to fill the void." *In re Propulsid Prods.*, 208 F.R.D. at 147. "'[T]he courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science, it does not lead it." *Id.* (quoting *Rosen v.*

Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996)).

In light of the differences that members of the Proposed Class would face with respect to the applicable state laws and the individual circumstances of their alleged injuries, as well as Plaintiff's failure to demonstrate that medical monitoring is necessary in this case, the Court finds that the Proposed Class is not cohesive, and certification of the class pursuant to Rule 23(b)(2) for purposes of medical monitoring is inappropriate.

B. Defendants' Motion to Strike the Class Action Allegations in the Amended Complaint

Defendants filed their motion to strike the class action allegations in the Amended Complaint before Plaintiff had moved to certify the Proposed Class. Plaintiff having subsequently filed her cross-motion, the Court does not need to address whether Defendants' motion was timely or premature. Because the Court finds that the Proposed Class should not be certified, it also finds that the class action allegations in the Amended Complaint should be stricken.

III. CONCLUSION

For the above reasons, Defendants' motion to strike the class action allegations in the Amended Complaint is granted, and Plaintiff's cross-motion for class certification is denied. An appropriate form of order is filed herewith.

Dated: May 31, 2006

s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.